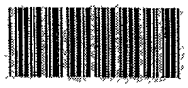
#4

VWAVE.001CP2

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Frank R. Miele, et al.
Appl. No.	:	09/815,982
Filed	:	March 22, 2001
For	:	**METHOD AND APPARATUS FOR THE NONINVASIVE ASSESSMENT OF HEMODYNAMIC PARAMETERS INCLUDING BLOOD VESSEL LOCATION**
Examiner	:	Unknown
Group Art Unit:		3736



27299
PATENT TRADEMARK OFFICE

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on

September 4, 2001
(Date)

Robert F. Gazdzinski
Reg. No. 39,990

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Before a first examination on the merits, please amend the above-identified application as follows:

IN THE SPECIFICATION

On page 1, line 12 of the specification, after "... patent application No.", please insert -- 09/815,080 --;

On page 36, line 6 of the specification, after "... Serial No.", please insert -- 09/815,080 --;

IN THE CLAIMS

Please amend Claims 1 and 7 as follows:

1. A method of locating a blood vessel disposed within surrounding tissue, comprising:

transmitting acoustic energy into said tissue including said blood vessel;

evaluating reflections of said acoustic energy [as a function of propagation of said energy within] from said tissue and said blood vessel, and

identifying at least one region of reduced energy reflection within said tissue, said at least one region corresponding to said blood vessel.

7. A method of [detecting] locating at least one wall of a blood vessel, comprising:

transmitting acoustic energy into the blood vessel;

detecting at least one region associated with the lumen in said blood vessel; and

detecting the location of said at least one wall of the blood vessel relative to said lumen;

wherein the act of detecting the location comprises analyzing A-mode data derived from said act of transmitting.

Additionally, please add Claims 10-40 as follows:

10. The method of Claim 1, wherein the act of identifying comprises:

determining a power metric from said reflections;

integrating said power metric to produce a power function;

normalizing said power function;

dividing said normalized power function into a plurality of intervals; and

evaluating at least one of said intervals to identify said artifact.

11. The method of Claim 7, wherein the act of detecting at least one region comprises analyzing the power of reflected by said blood vessel and associated lumen as a function of position.

12. The method of Claim 7, wherein the act of detecting the location comprises analyzing said A-mode data for variations in reflected power in at least one location relative to said lumen.

13. The method of Claim 12, wherein said act of analyzing said A-mode data for variations comprises comparing the reflected power in said at least one location to that associated with said lumen.

14. The method of Claim 13, wherein said act of comparing comprises comparing the reflected power corresponding to said at least one location to the mean power associated with at least a portion of said lumen.

15. The device of Claim 9, further comprising at least one second transducer adapted to generate second signals relating to the pressure on at least one face thereof.

16. The device of Claim 15, wherein said first signals are further utilized to determine a transfer function, said transfer function being used to correct said pressure measured by said at least one second transducer.

17. The device of Claim 9, wherein said processor is configured to analyze the integrated power profile associated with said echoes in order to determine the location of said lumen.

18. The device of Claim 9, wherein said processor is configured to analyze the signal level of said echoes in order to determine the location of said lumen.

19. Blood vessel locating apparatus, comprising:

at least one transducer capable of transmitting an acoustic wave into a blood vessel and receiving a plurality of echoes therefrom, said first transducer configured to generate first signals related to said echoes; and

a processor, operatively connected to said first transducer, and configured to process said first signals to determine the location of the lumen of said blood vessel.

20. The apparatus of Claim 19, wherein said processor is adapted to determine a power profile associated with said echoes, and identify at least one artifact therein, said at least one artifact corresponding at least in part to said lumen.

21. The apparatus of Claim 20, wherein said power profile is integrated over a variable corresponding to the propagation of said acoustic wave, and said at least one artifact comprises a plateau within said integrated power profile.

22. The apparatus of Claim 19, wherein said processor is adapted to determine the Doppler shift associated with blood present in said blood vessel.

23. The apparatus of Claim 19, wherein said processor is adapted to compare the signal level of at least a portion of said echoes and identify at least one artifact therein.

24. The apparatus of Claim 23, wherein said signal level comprises an envelope-squared metric, and said at least one artifact comprises a reduction in the magnitude of said envelope-squared metric, said reduction corresponding to said lumen of said blood vessel.

25. An information storage device, comprising;

a data storage medium;

a plurality of data stored on said medium, said plurality of data comprising a computer program adapted to run on a data processor, said computer program being configured for:

initiating the transmission of acoustic energy into the tissue of a subject including said blood vessel;

evaluating reflections of said acoustic energy from said tissue, and

identifying at least one region of reduced energy reflection within said tissue, said at least one region corresponding to a blood vessel.

26. The information storage device of Claim 25, wherein said computer program is adapted to generate a plurality of A-mode lines based on said reflections.

27. The information storage device of Claim 25, wherein said computer program is adapted to identify said at least one region of reduced energy reflection by integration of the power reflected by said tissue, including said blood vessel, said integration including at least one artifact indicative of the lumen of said blood vessel.

28. A method of positioning a device with respect to a blood vessel of a subject, comprising:

positioning an acoustic energy source with respect to said blood vessel;

transmitting acoustic energy from said source into said blood vessel;

receiving reflections of said acoustic energy from said blood vessel,

determining the relative wall positions of said blood vessel based on said received reflections; and

positioning said device with respect to said blood vessel based at least in part on said relative wall positions.

29. The method of Claim 28, wherein said act of determining the wall relative positions comprises:

detecting the lumen of said blood vessel;

evaluating said received reflections to identify a first wall relative to said lumen; and

evaluating said received reflections to identify a second wall relative to said lumen.

30. The method of Claim 29, further comprising determining the diameter of said blood vessel based on said identification of said first and second walls, and wherein the act of positioning said device with respect to said blood vessel comprises positioning said acoustic energy source so as to maintain said value of said diameter substantially at a predetermined value, the position of said device bearing some known relationship to the position of said acoustic energy source.

31. The method of Claim of Claim 30, wherein said act of maintaining said diameter substantially at a predetermined value comprises maintaining said value substantially maximized.

32. A method of positioning a device with respect to a blood vessel of a subject, comprising:

positioning an acoustic energy source with respect to said blood vessel;

transmitting acoustic energy from said source into said blood vessel;

receiving reflections of said acoustic energy from said blood vessel,

detecting the lumen associated with the blood vessel; and

positioning said device with respect to said blood vessel based at least in part on said lumen position.

33. The method of Claim 32, wherein the act of detecting the lumen comprises:

identifying at least one artifact within the integrated power profile of said received reflections, said at least one artifact corresponding to said lumen.

34. The method of Claim 33, wherein the act of identifying at least one artifact comprises:

determining a power metric;

integrating said power metric to produce a power function;

normalizing said power function;

dividing said normalized power function into a plurality of intervals; and

evaluating at least one of said intervals to identify said artifact.

35. The method of Claim 34, wherein said act of determining a power metric comprises deriving a metric based on an envelope-squared function.

36. A method of locating a blood vessel disposed within surrounding tissue, comprising the steps of:

transmitting acoustic energy into said tissue including said blood vessel to generate reflections thereof;

receiving said reflections of said acoustic energy from said tissue and said blood vessel;

forming at least one integrated power representation to identify at least one region of reduced energy reflection within said tissue, said at least one region corresponding to the lumen of said blood vessel; and

locating said blood vessel based on the location of said lumen.

37. Blood vessel locating apparatus, comprising:

transducer means adapted for transmitting an acoustic wave into a blood vessel and receiving a plurality of echoes therefrom, said transducer means configured to generate first signals related to said echoes; and

means for data processing operatively connected to said first transducer and configured for processing said first signals; and

computer program means adapted to run on said means for data processing, said computer program means further being adapted to determine the location of the lumen of said blood vessel based on a power profile derived at least in part from said first signals.

38. Blood vessel locating apparatus, comprising:

at least one transducer capable of transmitting an acoustic wave into a blood vessel and receiving a plurality of echoes therefrom, said first transducer configured to generate first signals related to said echoes;

at least one signal converter, operatively coupled to said at least one transducer and adapted to produce second signals from said first signals;

at least one digital processor, operatively coupled to said analog-to-digital converter, and configured to process said second signals; and

a computer program running at least in part on said digital processor, said computer program being adapted to determine a power profile based on said second signals, and to determine the location of the lumen of said blood vessel based at least in part on one or more artifacts present within said power profile.

39. A method of providing treatment to a living subject, comprising:

locating at least one blood vessel of said subject, said act of locating comprising locating the lumen associated with said at least one blood vessel by identifying at least one artifact within the integrated power profile of reflected acoustic energy transmitted into said blood vessel;

monitoring the blood pressure within said at least one blood vessel non-invasively; and

providing treatment to said subject based at least in part on said act of monitoring.

40. A method of providing treatment to a living subject, comprising:

locating at least one blood vessel of said subject, said act of locating comprising:

(i) locating the lumen associated with said at least one blood vessel by identifying at least one artifact within the integrated power profile of reflected acoustic energy transmitted into said blood vessel; and

(ii) locating the walls of said at least one blood vessel based at least in part on said power profile;

positioning a blood pressure monitoring device substantially over said at least one blood vessel based on said acts of locating the lumen and walls;

monitoring the blood pressure within said at least one blood vessel non-invasively; and

providing treatment to said subject based at least in part on said act of monitoring.

REMARKS

Amendments to pages 1 and 36 include inserted information which was not available at the time of filing with regard to the application number of a related U.S. patent application. Applicant submits that information inserted or deleted in these replacement pages does not constitute new matter. Replacement pages 1 and 36 are submitted herewith for filing in the above-referenced application.

Claims 1-9 were pending in the application. By this paper, Applicant has amended Claims 1 and 7, and added new Claims 10-40. Accordingly, Claims 1-40 are presented herein for examination.

Applicant's amendment to Claim 1 broadens the scope of the claim. The amendment to Claim 7 is made merely to more clearly and accurately describe the operation of Applicant's invention (i.e., location of the wall).

Applicant has herein also amended the specification to include the serial number of the related application referenced therein. None of these amendments add new matter.

Applicant hereby specifically reserves the right to prosecute claims of different or broader scope in a continuation or divisional application.

Applicant notes that any amendments or additions made herein are made solely for the purposes of more clearly and particularly describing and claiming the invention, and not for purposes of overcoming art or for patentability. The Examiner should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Examiner, based on such amendments or additions.

If the Examiner has any questions or comments which may be resolved over the telephone, he is requested to call the undersigned at (858) 505-1166.

Respectfully submitted,

GAZDZINSKI & ASSOCIATES

Dated: September 4, 2001

By: _____

Robert F. Gazdzinski
Registration No. 39,990
3914 Murphy Canyon Road, Suite A232
San Diego, CA 92123
Telephone No.: (858) 505-1166
Facsimile No.: (858) 505-1168

METHOD AND APPARATUS FOR THE NONINVASIVE ASSESSMENT OF HEMODYNAMIC PARAMETERS INCLUDING BLOOD VESSEL LOCATION

This application is a continuation-in-part of U.S. patent application No. 09/342,549 entitled "Method And Apparatus For The Noninvasive Determination Of Arterial Blood Pressure" filed June 29, 1999, and assigned to the Applicant herein.

Related Applications

This application is related to U.S. patent application No. 09/489,160 entitled "Method And Apparatus For The Noninvasive Determination Of Arterial Blood Pressure" filed January 21, 2001, and U.S. patent application No. 09/815,080 entitled "Method and Apparatus for Assessing Hemodynamic Parameters within the Circulatory System of a Living Subject" filed contemporaneously herewith, both assigned to the Assignee hereof.

Background of the Invention

Field of the Invention

This invention relates generally to methods and apparatus for monitoring the hemodynamic parameters of a living subject, and specifically to the non-invasive monitoring of arterial blood pressure using acoustic techniques.

Description of the Related Art

Three well known techniques have been used to non-invasively monitor a subject's arterial blood pressure waveform, namely, auscultation, oscillometry, and tonometry. Both the auscultation and oscillometry techniques use a standard inflatable arm cuff that occludes the subject's brachial artery. The auscultatory technique determines the subject's systolic and diastolic pressures by monitoring certain Korotkoff sounds that occur as the cuff is slowly deflated. The oscillometric technique, on the other hand, determines these pressures, as well as the subject's mean pressure, by measuring actual pressure changes that occur in the cuff as the cuff is deflated. Both

Specifically, in one exemplary application, backscattered acoustic energy is analyzed to initially locate the blood vessel which is embedded within the surrounding tissue of the subject. In another application, the backscattered energy is used to maintain a sensing or treatment apparatus (e.g., the pressure and/ultrasonic transducers assembly 800 of the NIBP device previously described herein, or that described in Assignee's co-pending U.S. patent application Serial No. 09/815,080 entitled "Method and Apparatus for Assessing Hemodynamic Parameters Within the Circulatory System of a Living Subject" filed contemporaneously herewith, and incorporated by reference herein in its entirety) in optimal position with respect to the blood vessel.

In one embodiment, the method of detecting and locating the blood vessel of interest is accomplished by directly detecting the lumen associated with the blood vessel based on reduced levels of backscattered ultrasonic energy present in "A-mode" line scans; ultrasonic energy is more readily absorbed within the lumen (such as by the red blood cells and plasma present within the blood) than by the surrounding vessel walls and tissue. Hence, the vessel is located, and/or the monitoring device positioned, by identifying regions of reduced backscattered energy. Such regions may be found in one dimension (e.g., only in terms of depth within the tissue), or multiple dimensions, such as where it is desired to precisely locate the vessel both in terms of lateral or transverse position and depth.

Another embodiment of the invention detects the relative locations of both the front and rear walls of the blood vessel based on analysis of backscattered A-mode energy. This wall information is used to indirectly determine the effective diameter of the blood vessel; the variation in blood vessel diameter as a function of lateral or transverse position is then used to identify the optimal lateral position of the measurement or treatment device.

Note that the act of "lateral" positioning as described herein may also include some component of longitudinal positioning (i.e., along the longitudinal axis of the blood vessel), since placement of the apparatus on the wrist/forearm of the subject is governed more by the physical attributes of the wrist, as opposed to the orientation of the blood vessel within the wrist/forearm. Specifically, in the cases where the point of measurement for the transducer(s) occurs at a location where the radial artery runs in a

Revised Claims as of September 4, 2001 (Pages 67 through 68e)

1. A method of locating a blood vessel disposed within surrounding tissue, comprising:

transmitting acoustic energy into said tissue including said blood vessel;

evaluating reflections of said acoustic energy from said tissue and said blood vessel, and

identifying at least one region of reduced energy reflection within said tissue, said at least one region corresponding to said blood vessel.

2. The method of Claim 1, wherein said act of evaluating comprises analyzing at least one A-mode line.

3. The method of Claim 2, further comprising correlating said at least one region to a depth location within said tissue based on said act of analyzing said at least one A-mode line.

4. The method of Claim 1, wherein said act of identifying comprises:

forming at least one integrated power representation based on said reflections; and

identifying at least one artifact within said at least one integrated power representation, said at least one artifact corresponding to the lumen of said blood vessel.

5. The method of Claim 4, wherein the act of identifying at least one artifact comprises identifying at least one plateau within a normalized integrated power profile.

6. The method of Claim 1, wherein said act of identifying comprises:

measuring the signal level of said reflections as a function of depth within said tissue; and

identifying the lumen of said blood vessel based on at least one feature identified during said act of measuring.

7. A method of locating at least one wall of a blood vessel, comprising:

transmitting acoustic energy into the blood vessel;

detecting at least one region associated with the lumen in said blood vessel; and

detecting the location of said at least one wall of the blood vessel relative to said lumen;

wherein the act of detecting the location comprises analyzing A-mode data derived from said act of transmitting.

8. A method of locating a blood vessel in tissue, comprising:

generating at least one beam of acoustic waves;

transmitting said at least one beam of acoustic waves into said tissue, said beam moving with respect to said tissue so as to ensonify different portions of said tissue as a function of time;

receiving energy backscattered by said tissue and said blood vessel;

analyzing said backscattered energy to identify at least one artifact therein, said at least one artifact resulting from the lumen of said blood vessel; and

correlating said at least one artifact to the location of said blood vessel.

9. A device, comprising:

at least one transducer capable of transmitting an acoustic wave into a blood vessel and receiving a plurality of echoes therefrom, said first transducer configured to generate first signals related to said echoes;

a processor, operatively connected to said first transducer, and configured to process said first signals to determine the location of the lumen of said blood vessel;

a positioning device adapted to receive at least a portion of said at least one transducer, and alter the position thereof with respect to said blood vessel; and

a controller, operatively connected to said positioning device, which controls said positioning device based at least in part on said location of said lumen relative to said at least one transducer.

10. The method of Claim 1, wherein the act of identifying comprises:

determining a power metric from said reflections;

integrating said power metric to produce a power function;

normalizing said power function;

dividing said normalized power function into a plurality of intervals; and

evaluating at least one of said intervals to identify said artifact.

11. The method of Claim 7, wherein the act of detecting at least one region comprises analyzing the power of reflected by said blood vessel and associated lumen as a function of position.

12. The method of Claim 7, wherein the act of detecting the location comprises analyzing said A-mode data for variations in reflected power in at least one location relative to said lumen.

13. The method of Claim 12, wherein said act of analyzing said A-mode data for variations comprises comparing the reflected power in said at least one location to that associated with said lumen.

14. The method of Claim 13, wherein said act of comparing comprises comparing the reflected power corresponding to said at least one location to the mean power associated with at least a portion of said lumen.

15. The device of Claim 9, further comprising at least one second transducer adapted to generate second signals relating to the pressure on at least one face thereof.

16. The device of Claim 15, wherein said first signals are further utilized to determine a transfer function, said transfer function being used to correct said pressure measured by said at least one second transducer.

17. The device of Claim 9, wherein said processor is configured to analyze the integrated power profile associated with said echoes in order to determine the location of said lumen.

18. The device of Claim 9, wherein said processor is configured to analyze the signal level of said echoes in order to determine the location of said lumen.

19. Blood vessel locating apparatus, comprising:

at least one transducer capable of transmitting an acoustic wave into a blood vessel and receiving a plurality of echoes therefrom, said first transducer configured to generate first signals related to said echoes; and

a processor, operatively connected to said first transducer, and configured to process said first signals to determine the location of the lumen of said blood vessel.

20. The apparatus of Claim 19, wherein said processor is adapted to determine a power profile associated with said echoes, and identify at least one artifact therein, said at least one artifact corresponding at least in part to said lumen.

21. The apparatus of Claim 20, wherein said power profile is integrated over a variable corresponding to the propagation of said acoustic wave, and said at least one artifact comprises a plateau within said integrated power profile.

22. The apparatus of Claim 19, wherein said processor is adapted to determine the Doppler shift associated with blood present in said blood vessel.

23. The apparatus of Claim 19, wherein said processor is adapted to compare the signal level of at least a portion of said echoes and identify at least one artifact therein.

24. The apparatus of Claim 23, wherein said signal level comprises an envelope-squared metric, and said at least one artifact comprises a reduction in the magnitude of said envelope-squared metric, said reduction corresponding to said lumen of said blood vessel.

25. An information storage device, comprising;

a data storage medium;

a plurality of data stored on said medium, said plurality of data comprising a computer program adapted to run on a data processor, said computer program being configured for:

initiating the transmission of acoustic energy into the tissue of a subject including said blood vessel;

evaluating reflections of said acoustic energy from said tissue, and

identifying at least one region of reduced energy reflection within said tissue, said at least one region corresponding to a blood vessel.

26. The information storage device of Claim 25, wherein said computer program is adapted to generate a plurality of A-mode lines based on said reflections.

27. The information storage device of Claim 25, wherein said computer program is adapted to identify said at least one region of reduced energy reflection by integration of the power reflected by said tissue, including said blood vessel, said integration including at least one artifact indicative of the lumen of said blood vessel.

28. A method of positioning a device with respect to a blood vessel of a subject, comprising:

positioning an acoustic energy source with respect to said blood vessel;

transmitting acoustic energy from said source into said blood vessel;

receiving reflections of said acoustic energy from said blood vessel,

determining the relative wall positions of said blood vessel based on said received reflections; and

positioning said device with respect to said blood vessel based at least in part on said relative wall positions.

29. The method of Claim 28, wherein said act of determining the wall relative positions comprises:

detecting the lumen of said blood vessel;

evaluating said received reflections to identify a first wall relative to said lumen; and

evaluating said received reflections to identify a second wall relative to said lumen.

30. The method of Claim 29, further comprising determining the diameter of said blood vessel based on said identification of said first and second walls, and wherein the act of positioning said device with respect to said blood vessel comprises positioning said acoustic energy source so as to maintain said value of said diameter substantially at a predetermined value, the position of said device bearing some known relationship to the position of said acoustic energy source.

31. The method of Claim of Claim 30, wherein said act of maintaining said diameter substantially at a predetermined value comprises maintaining said value substantially maximized.

32. A method of positioning a device with respect to a blood vessel of a subject, comprising:

positioning an acoustic energy source with respect to said blood vessel;

transmitting acoustic energy from said source into said blood vessel;

receiving reflections of said acoustic energy from said blood vessel,

detecting the lumen associated with the blood vessel; and

positioning said device with respect to said blood vessel based at least in part on said lumen position.

33. The method of Claim 32, wherein the act of detecting the lumen comprises:

identifying at least one artifact within the integrated power profile of said received reflections, said at least one artifact corresponding to said lumen.

34. The method of Claim 33, wherein the act of identifying at least one artifact comprises:

determining a power metric;

integrating said power metric to produce a power function;

normalizing said power function;

dividing said normalized power function into a plurality of intervals; and

evaluating at least one of said intervals to identify said artifact.

35. The method of Claim 34, wherein said act of determining a power metric comprises deriving a metric based on an envelope-squared function.

36. A method of locating a blood vessel disposed within surrounding tissue, comprising the steps of:

transmitting acoustic energy into said tissue including said blood vessel to generate reflections thereof;

receiving said reflections of said acoustic energy from said tissue and said blood vessel;

forming at least one integrated power representation to identify at least one region of reduced energy reflection within said tissue, said at least one region corresponding to the lumen of said blood vessel; and

locating said blood vessel based on the location of said lumen.

37. Blood vessel locating apparatus, comprising:

transducer means adapted for transmitting an acoustic wave into a blood vessel and receiving a plurality of echoes therefrom, said transducer means configured to generate first signals related to said echoes; and

means for data processing operatively connected to said first transducer and configured for processing said first signals; and

computer program means adapted to run on said means for data processing, said computer program means further being adapted to determine the location of the lumen of said blood vessel based on a power profile derived at least in part from said first signals.

38. Blood vessel locating apparatus, comprising:

at least one transducer capable of transmitting an acoustic wave into a blood vessel and receiving a plurality of echoes therefrom, said first transducer configured to generate first signals related to said echoes;

at least one signal converter, operatively coupled to said at least one transducer and adapted to produce second signals from said first signals;

at least one digital processor, operatively coupled to said analog-to-digital converter, and configured to process said second signals; and

a computer program running at least in part on said digital processor, said computer program being adapted to determine a power profile based on said second signals, and to determine the location of the lumen of said blood vessel based at least in part on one or more artifacts present within said power profile.

39. A method of providing treatment to a living subject, comprising:

locating at least one blood vessel of said subject, said act of locating comprising locating the lumen associated with said at least one blood vessel by identifying at least one artifact within the integrated power profile of reflected acoustic energy transmitted into said blood vessel;

monitoring the blood pressure within said at least one blood vessel non-invasively; and

providing treatment to said subject based at least in part on said act of monitoring.

40. A method of providing treatment to a living subject, comprising:

locating at least one blood vessel of said subject, said act of locating comprising:

(i) locating the lumen associated with said at least one blood vessel by identifying at least one artifact within the integrated power profile of reflected acoustic energy transmitted into said blood vessel; and

(ii) locating the walls of said at least one blood vessel based at least in part on said power profile;

positioning a blood pressure monitoring device substantially over said at least one blood vessel based on said acts of locating the lumen and walls;

monitoring the blood pressure within said at least one blood vessel non-invasively; and

providing treatment to said subject based at least in part on said act of monitoring.